

# ACTIQ MARKETING 2001

Andy Pyfer

February 2001

National Sales Meeting



PLAINTIFFS TRIAL  
EXHIBIT

**P-18898\_00001**

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**TEVA\_MDL\_A\_05313123**

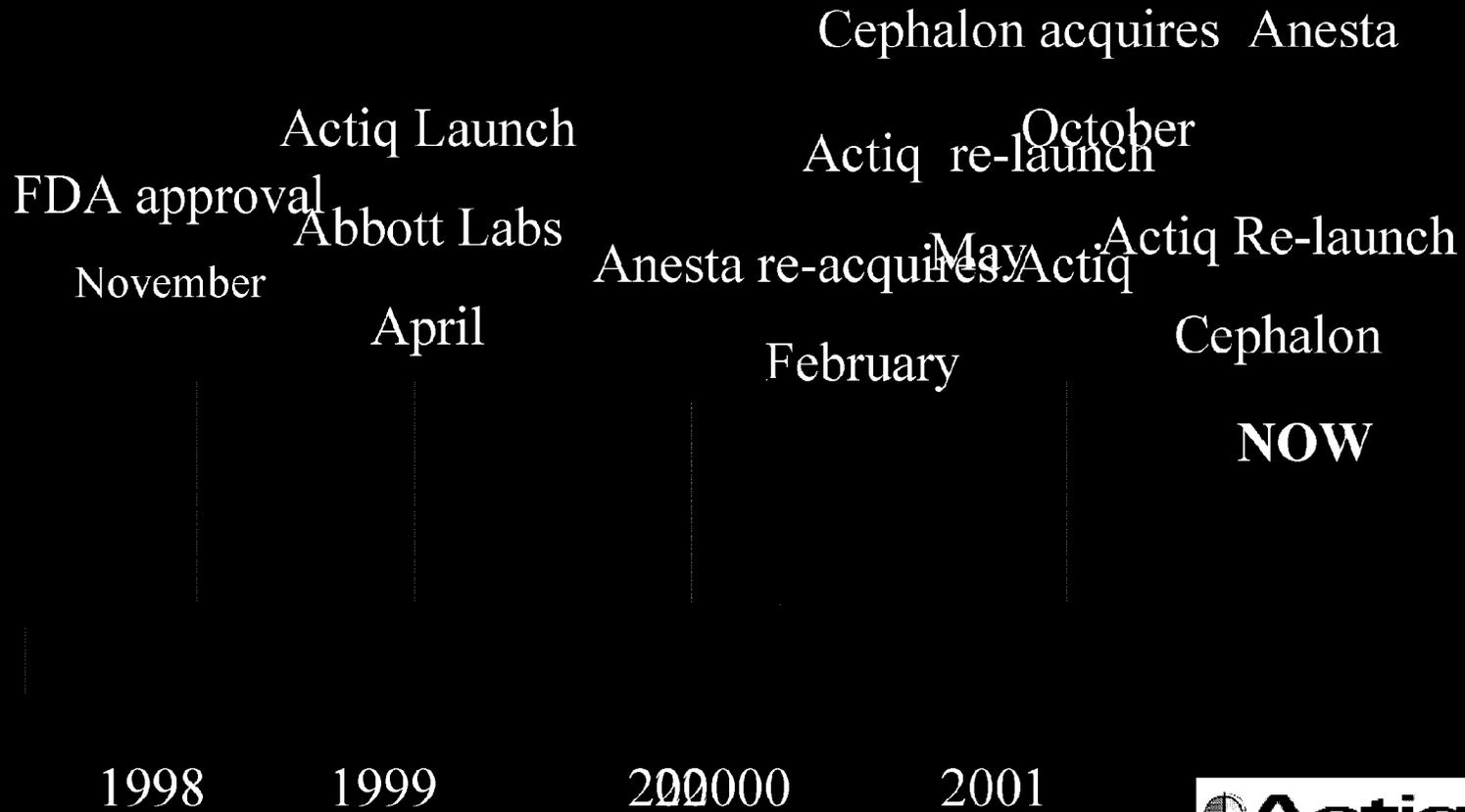
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# Actiq Marketing Overview: Key Topics

- I. Actiq History
- II. Opioid Market Review
- III. Actiq Sales Review/Analysis
- IV. Key Issues, Strategies and Tactics
- V. Keys to Success



# I. History of Actiq



# II. Opioid Market Review



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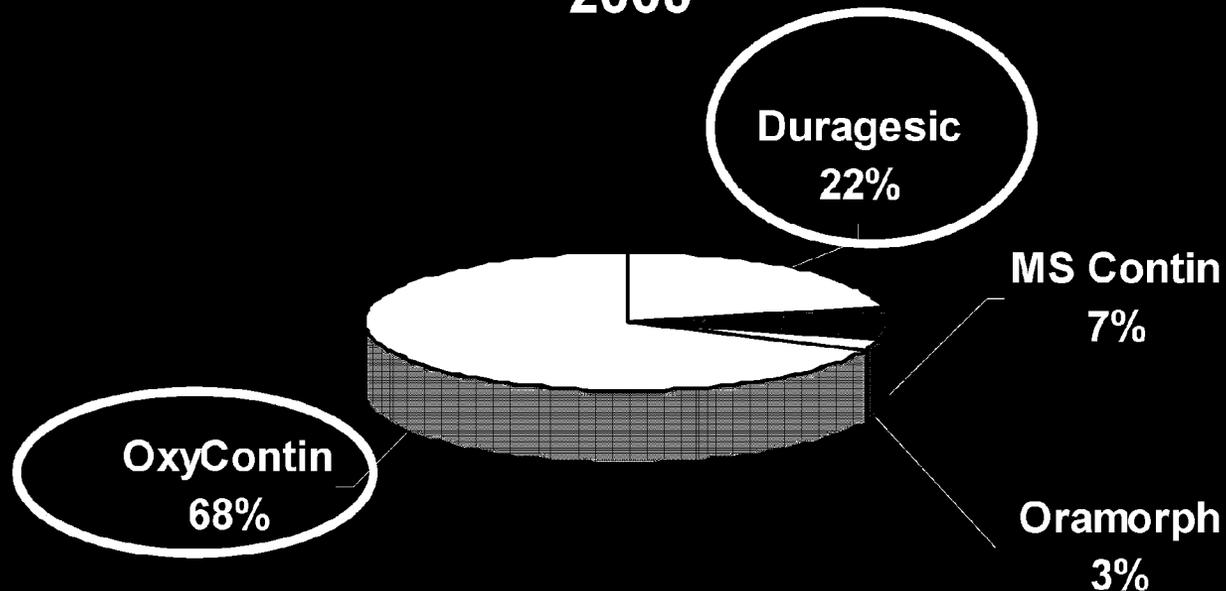
# Long Acting Opioids

<u>Long Acting Opioid</u>	<u>Generic</u>	<u>Company</u>
<b>Duragesic</b>	<b>transdermal fentanyl</b>	<b>Janssen</b>
<b>Oxycontin</b>	<b>oxycodone</b>	<b>Purdue</b>
<b>MS Contin</b>	<b>morphine</b>	<b>Purdue</b>
<b>Oramorph</b>	<b>morphine</b>	<b>Roxane</b>
<b>Kadian</b>	<b>morphine</b>	<b>Faulding</b>



# Long Acting Opioids

## Long Acting Opioid Retail TRx Count 2000



**Actiq**<sup>®</sup>  
(oral transmucosal  
fentanyl citrate)

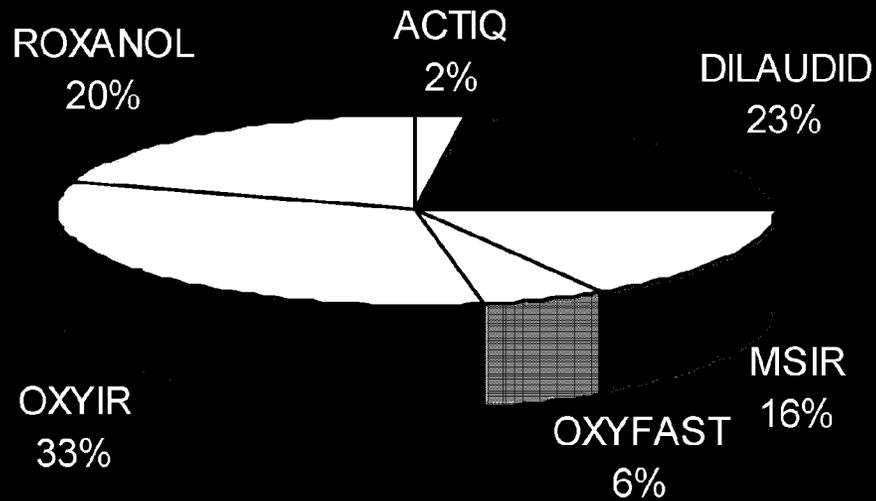
# Short Acting Opioids

<u>Short Acting Opioid</u>	<u>Generic</u>	<u>Company</u>
<b>Actiq</b>	<b>transmucosal fentanyl</b>	<b>Cephalon</b>
<b>OxyIR</b>	<b>oxycodone</b>	<b>Purdue</b>
<b>Oxyfast</b>	<b>oxycodone</b>	<b>Purdue</b>
<b>MSIR</b>	<b>morphine</b>	<b>Purdue</b>
<b>Roxanol</b>	<b>morphine</b>	<b>Roxane</b>
<b>Dilaudid</b>	<b>hydromorphone</b>	<b>Knoll</b>



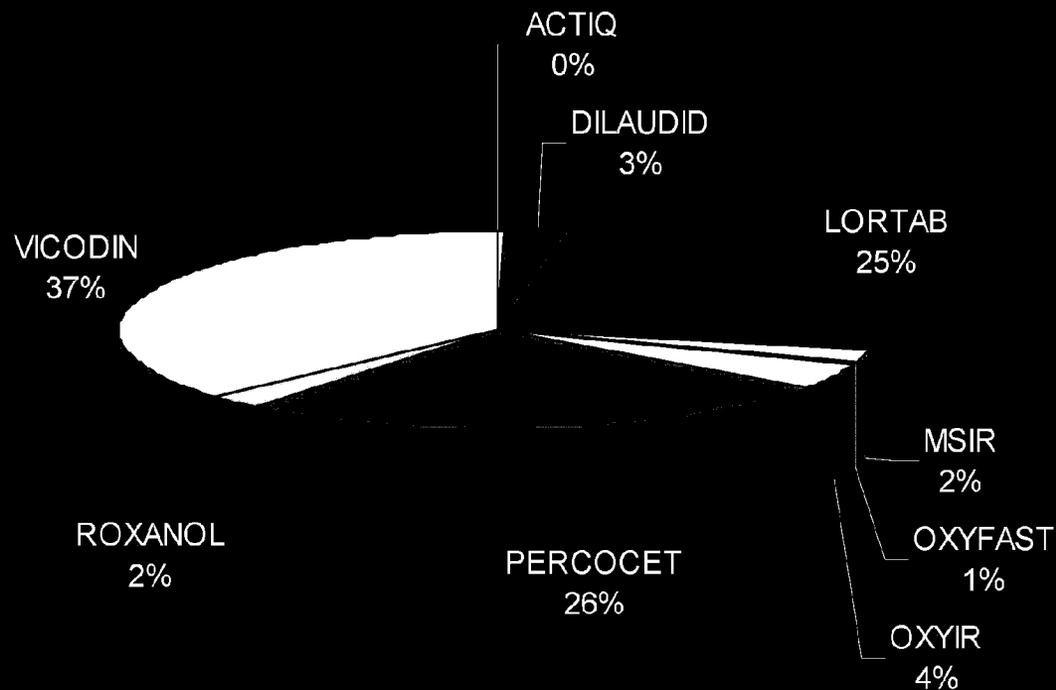
# Short Acting Opioids

## Pure Short Acting Opioid Retail TRx Count 2000



# Short Acting Opioids

## Short Acting Opioid Retail TRx Count 2000



# III. Actiq Sales Review/Analysis



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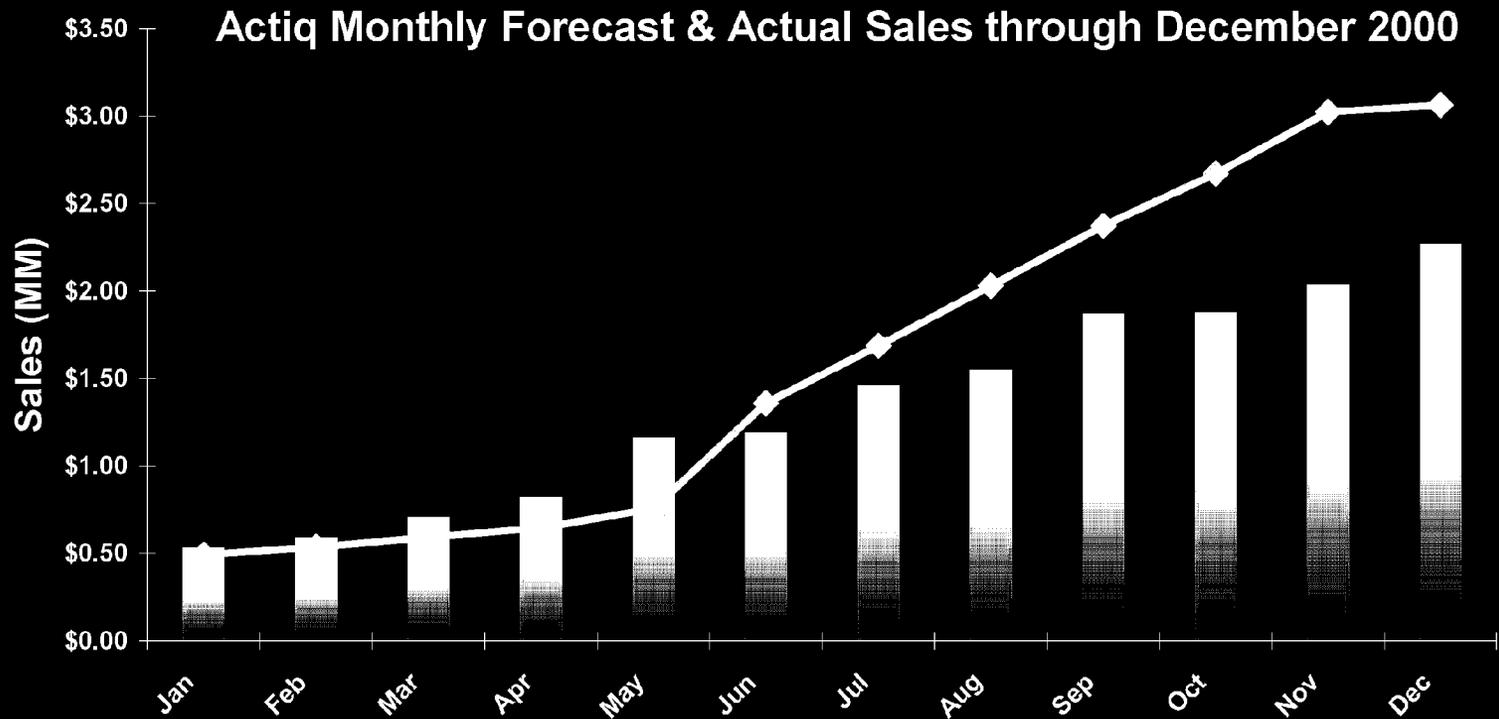
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# Actiq Monthly Sales



**Actiq**<sup>®</sup>  
(oral transmucosal  
fentanyl citrate)

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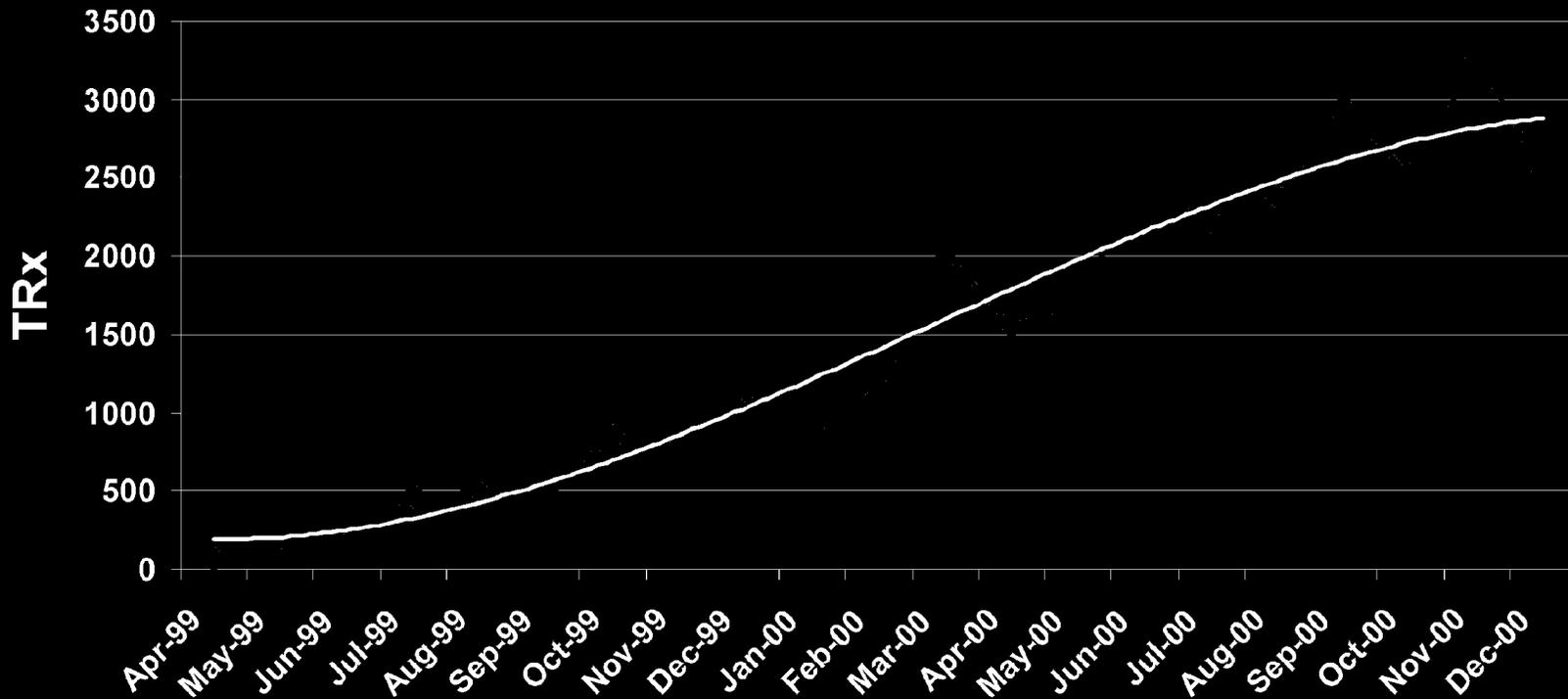
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# Actiq Monthly NPA TRx



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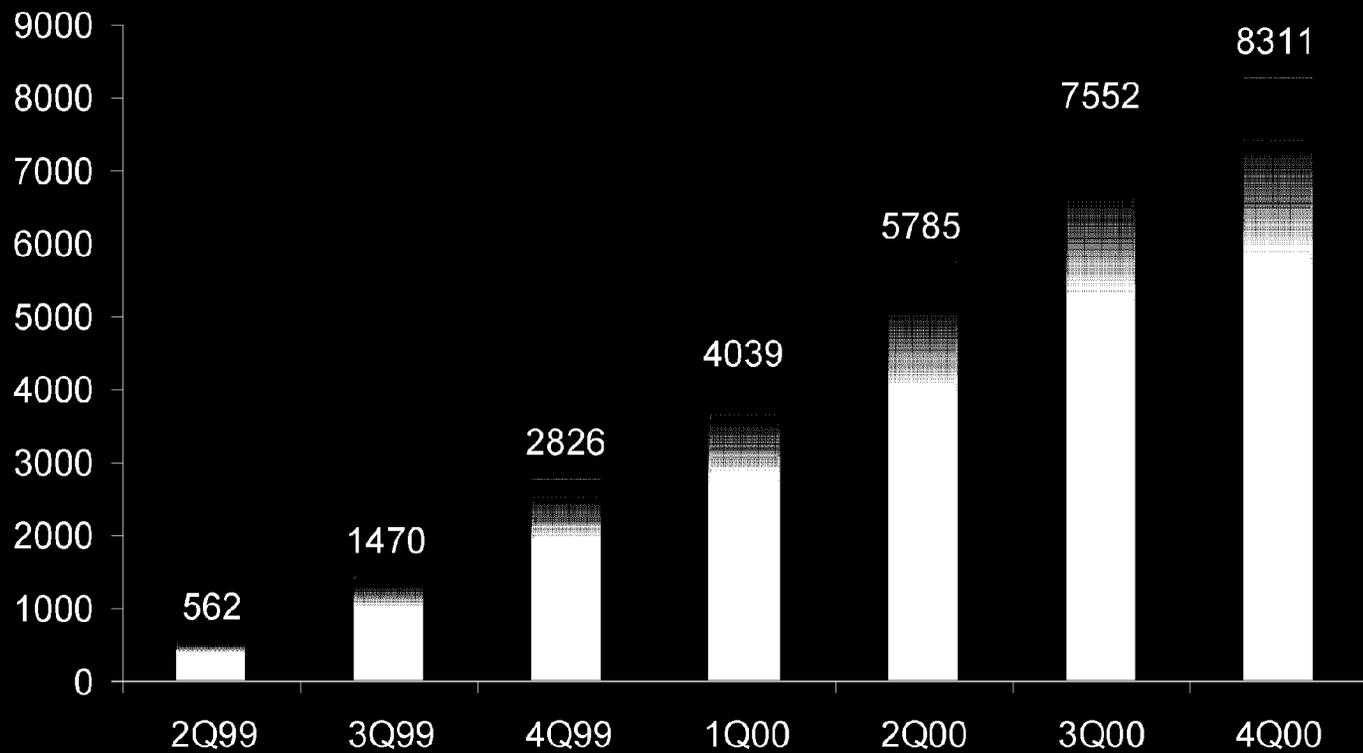
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# Actiq Quarterly TRx



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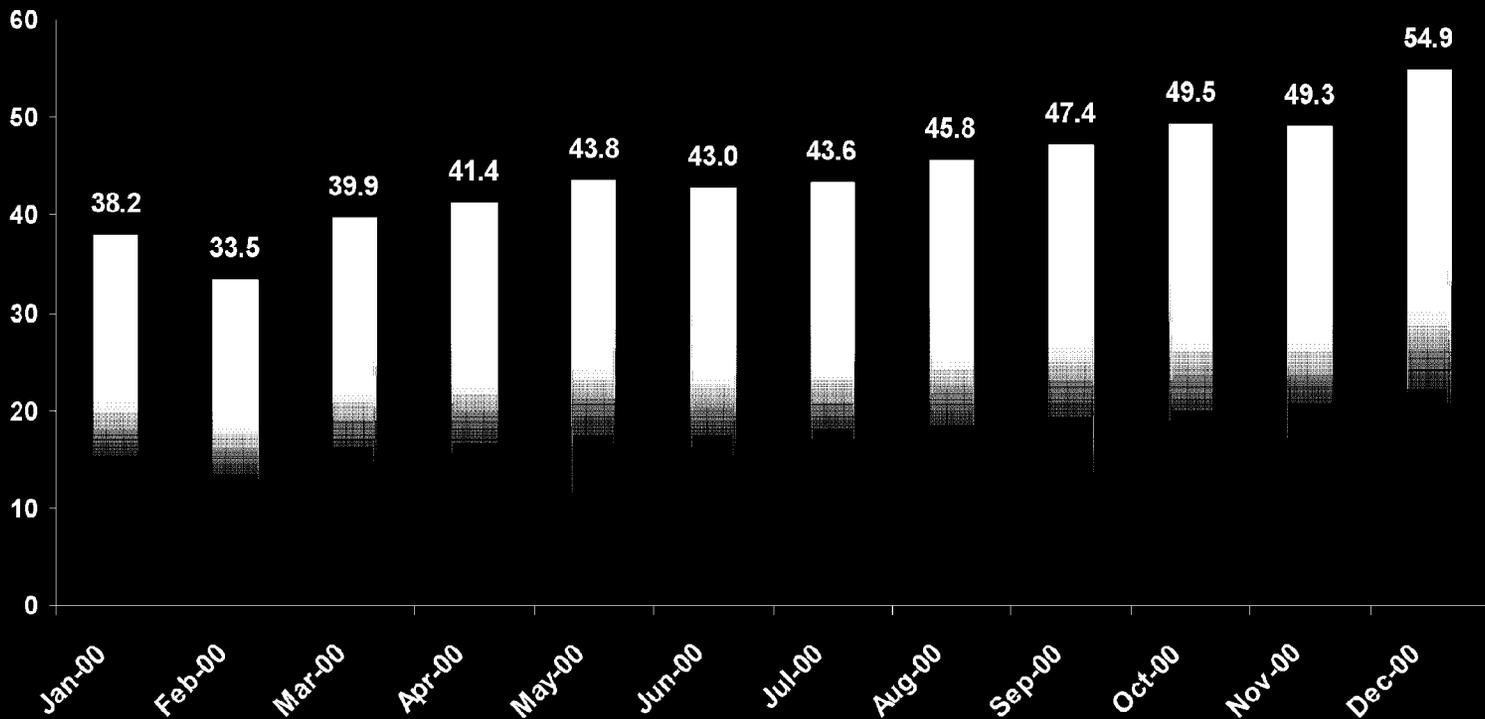
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# Actiq Units / Prescription



 **Actiq**<sup>®</sup>  
(oral transmucosal  
fentanyl citrate)

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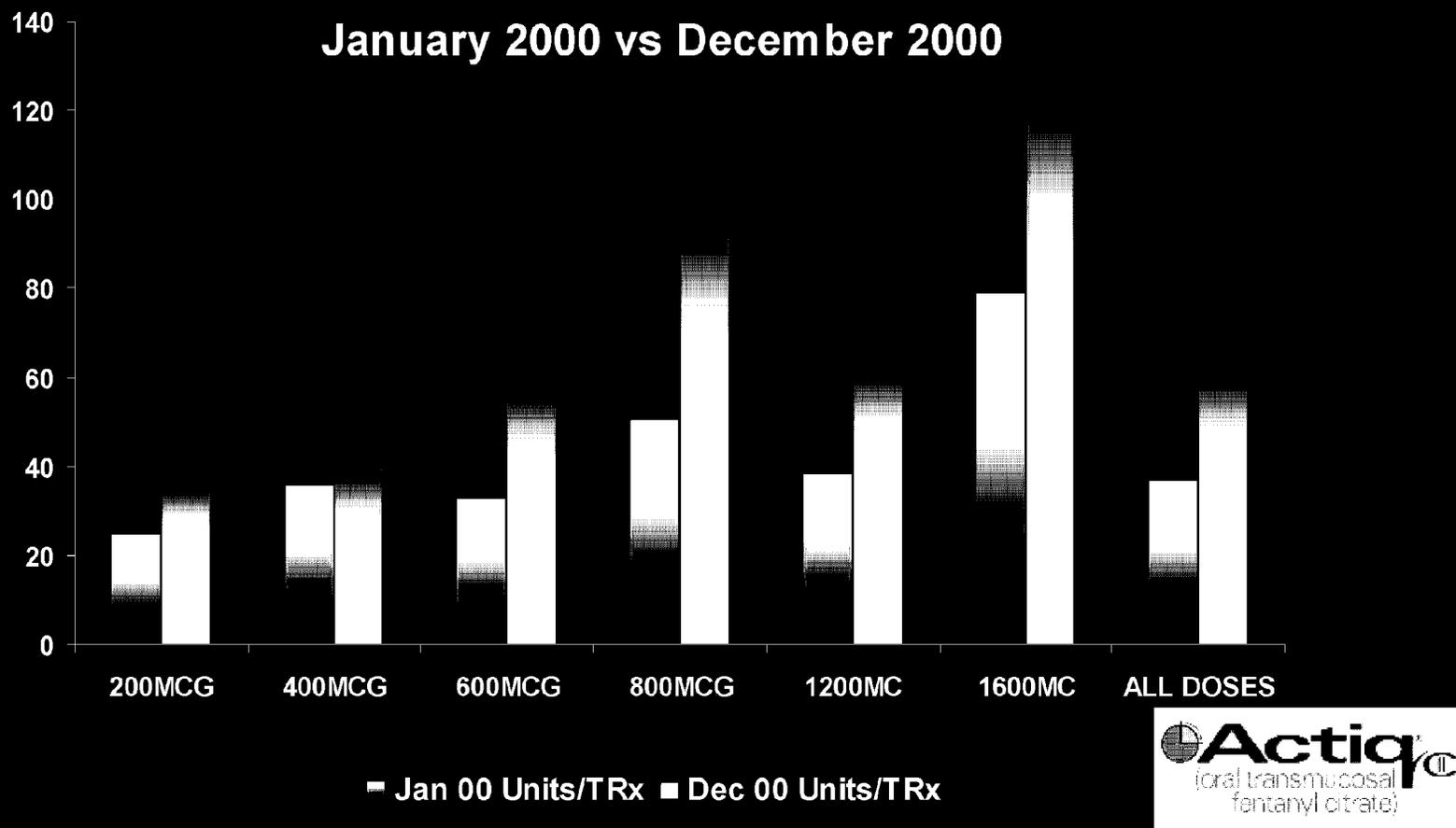
Confidential

CEPH-CT-DS-00191479  
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# Actiq Prescription Size by Strength



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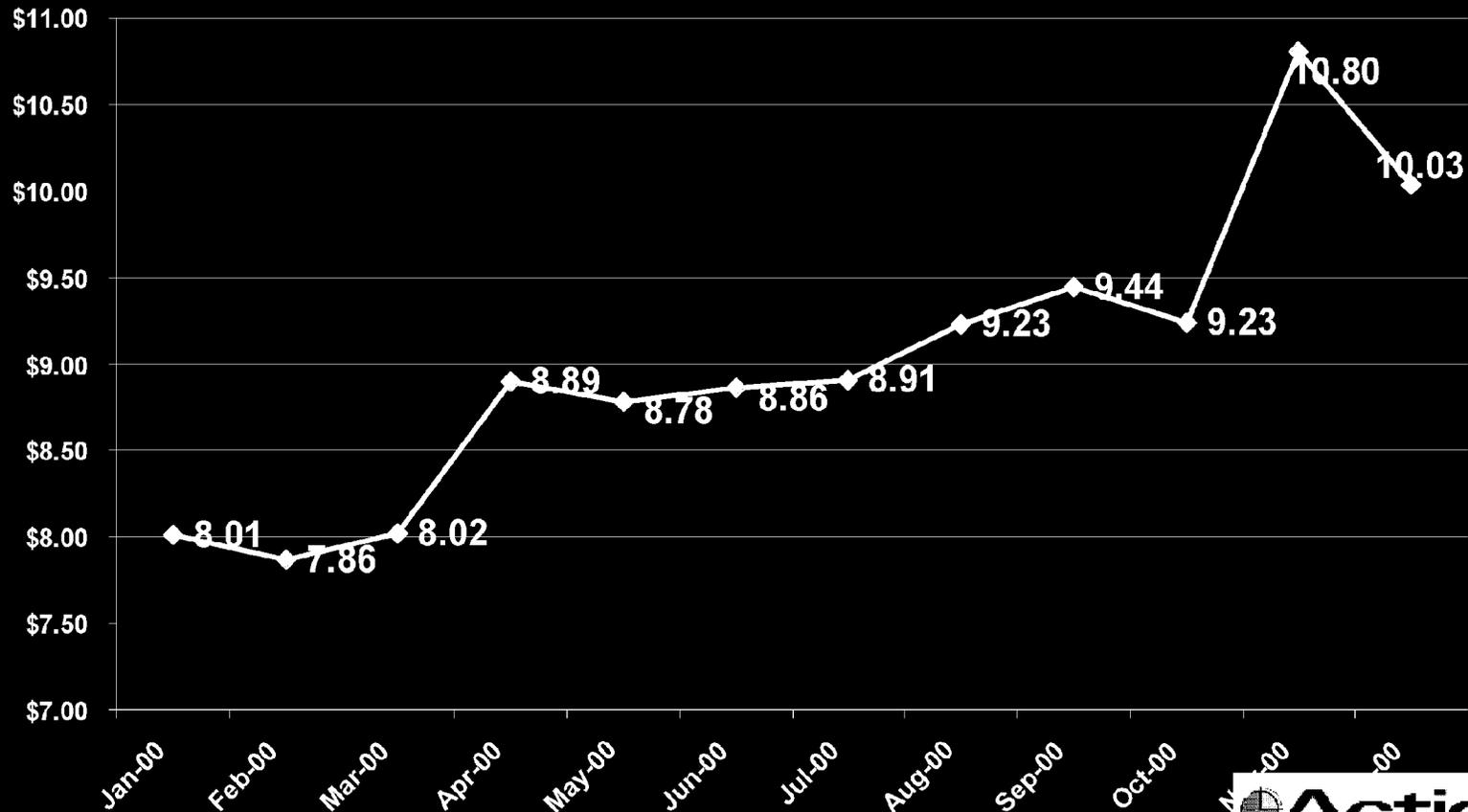
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# Factory Average Net Selling Price



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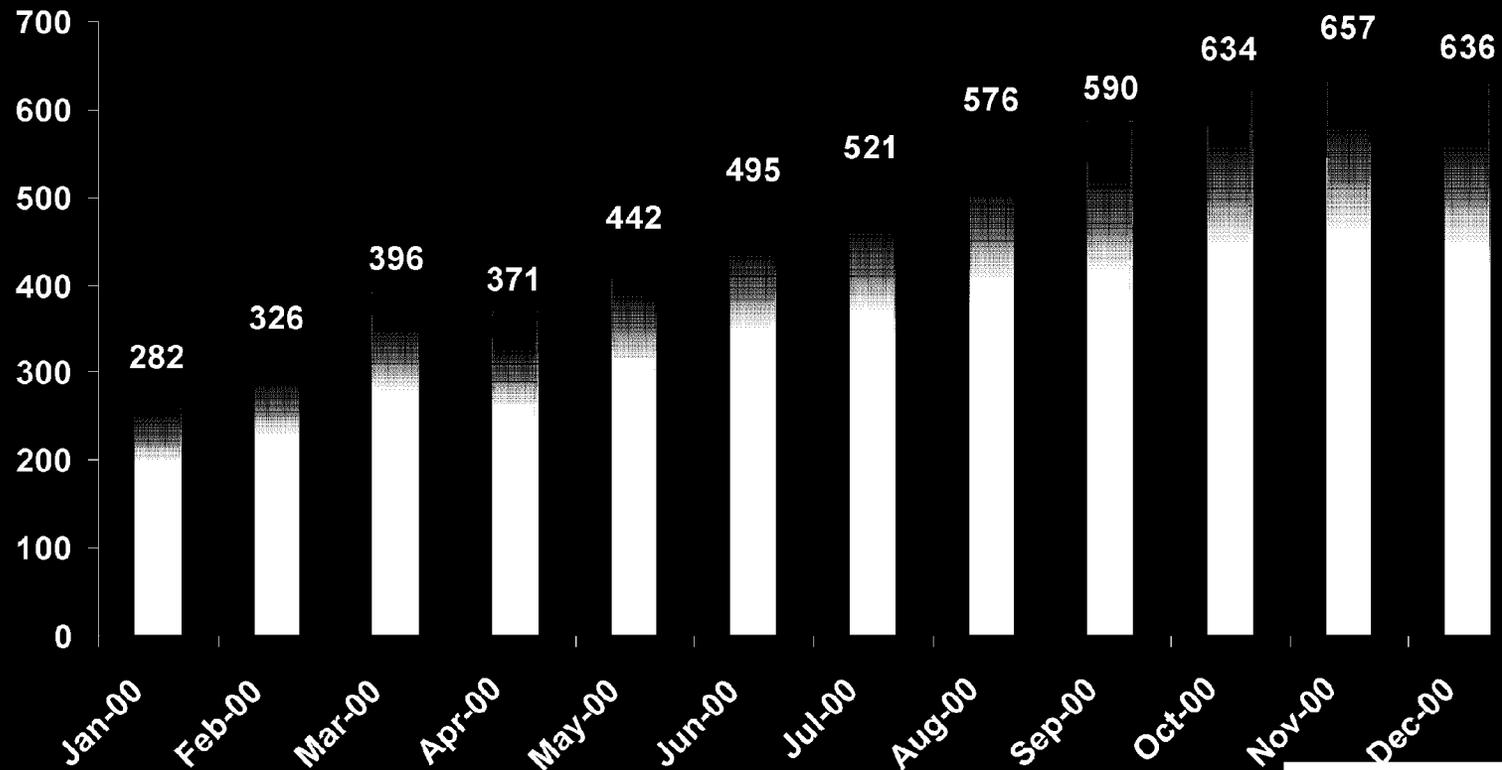
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# Actiq Prescriber Analysis

## Xponent – Monthly Prescribers



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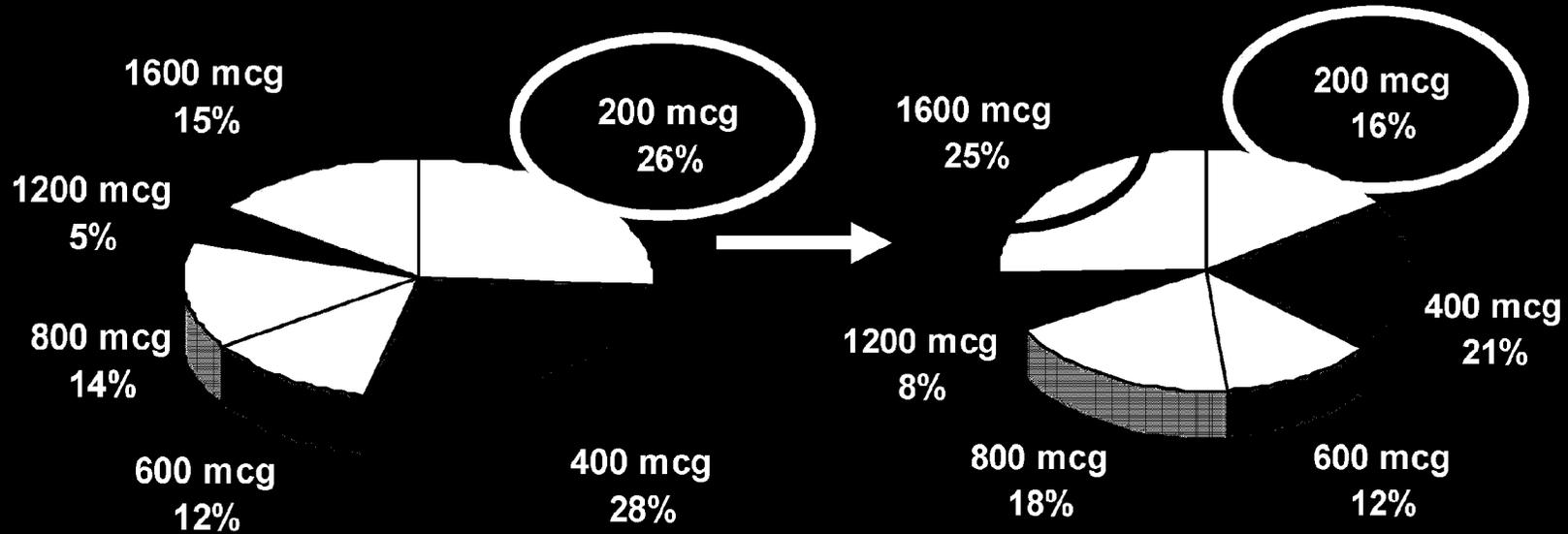
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# Percent Units by Strength

January 2000 Xponent

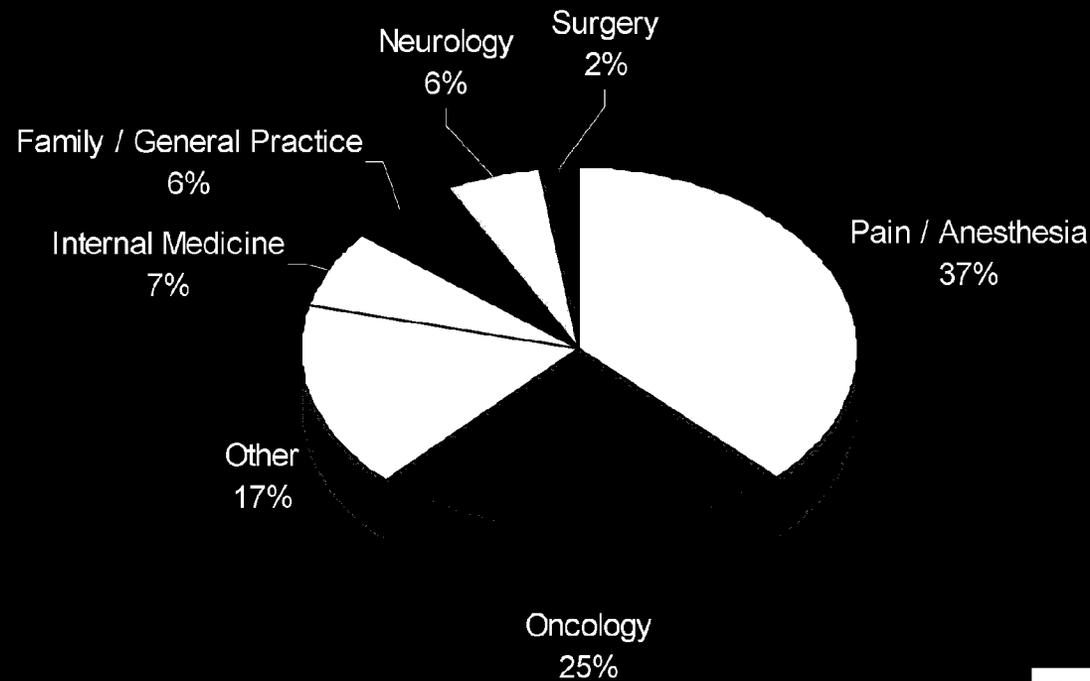
December 2000 Xponent



**Actiq**<sup>®</sup>  
(oral transmucosal  
fentanyl citrate)

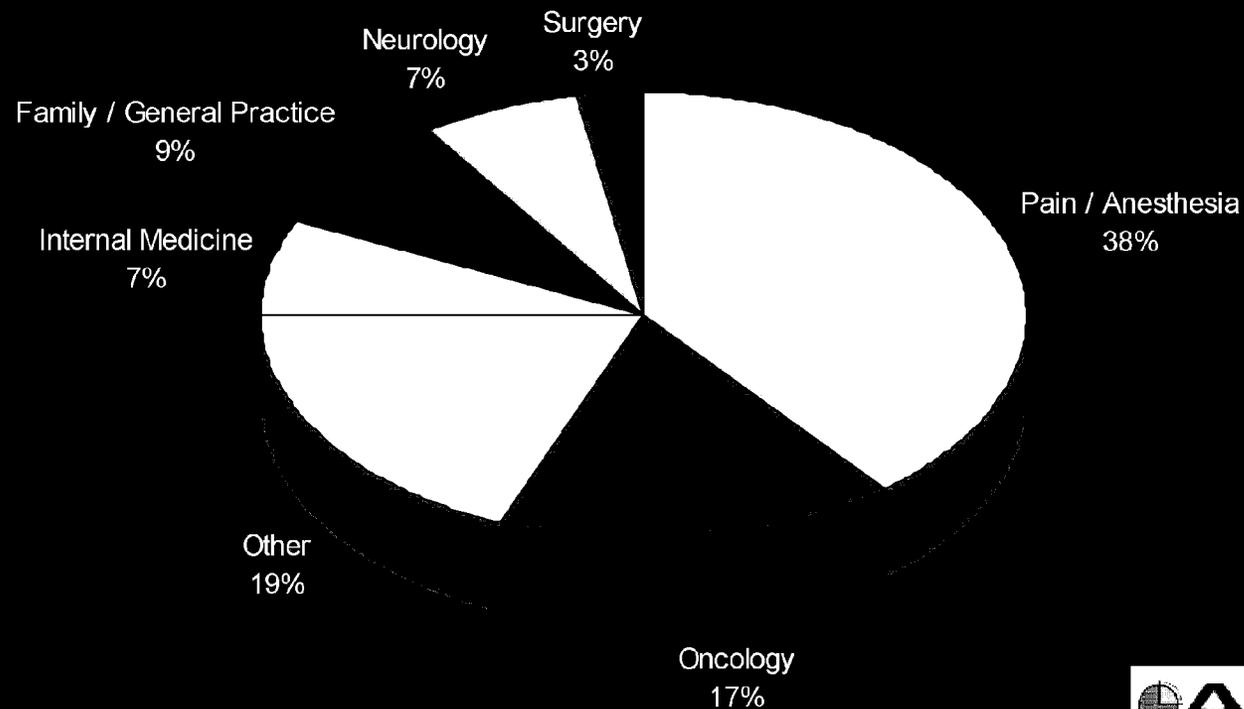
# Actiq Prescriber Analysis

## Xponent YTD TRx by Specialty



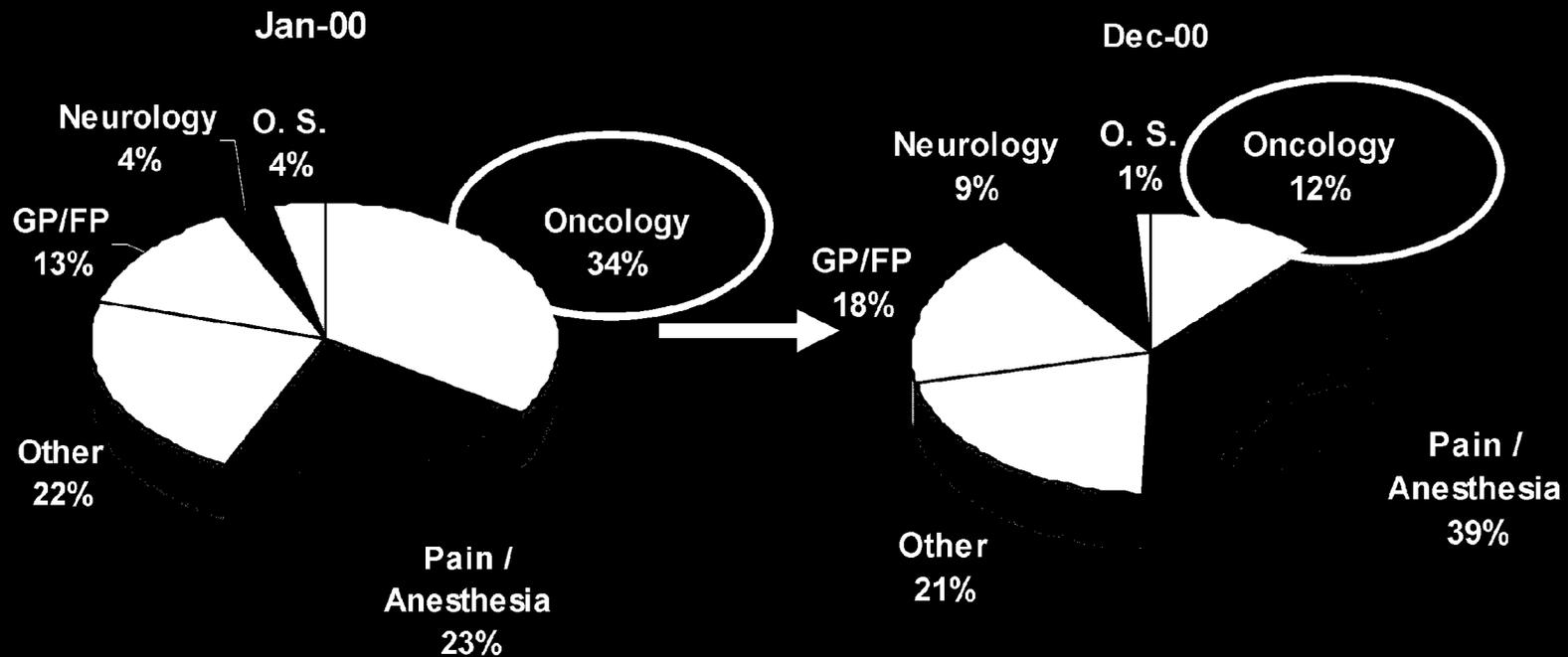
# Actiq Prescriber Analysis

## Xponent – Total Units YTD by Specialty



# Actiq Prescriber Analysis

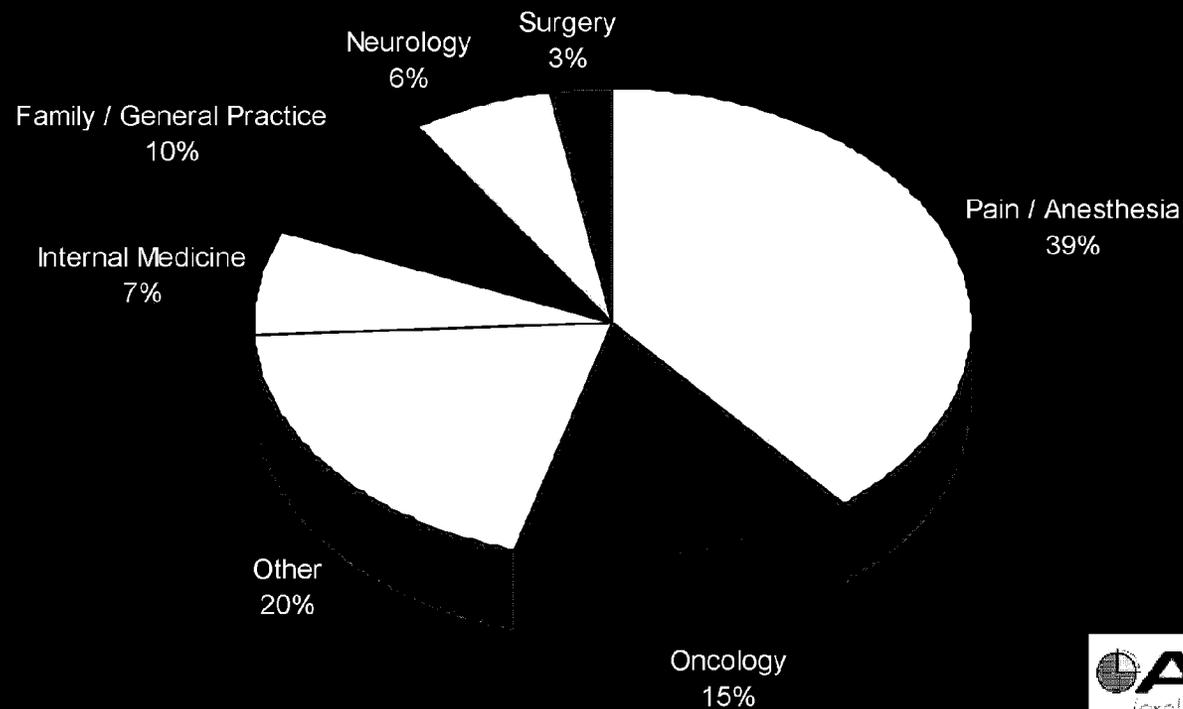
## Xponent - % Units by Specialty



**Actiq**<sup>®</sup>  
(oral transmucosal  
fentanyl citrate)

# Actiq Prescriber Analysis

## Xponent – Total Sales YTD by Specialty



**Actiq**<sup>®</sup>  
(oral transmucosal  
fentanyl citrate)

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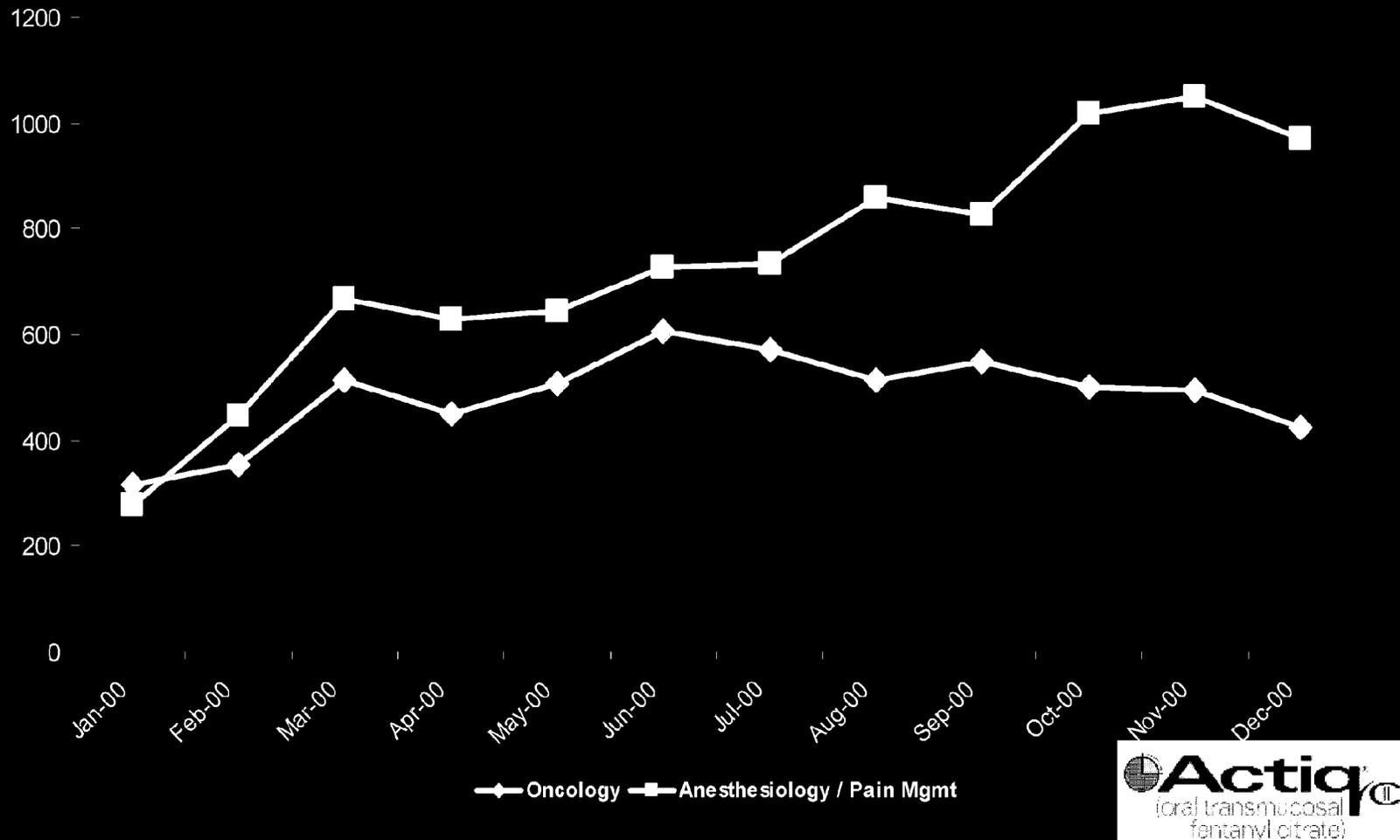
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# Xponent – Monthly TRx by Specialty



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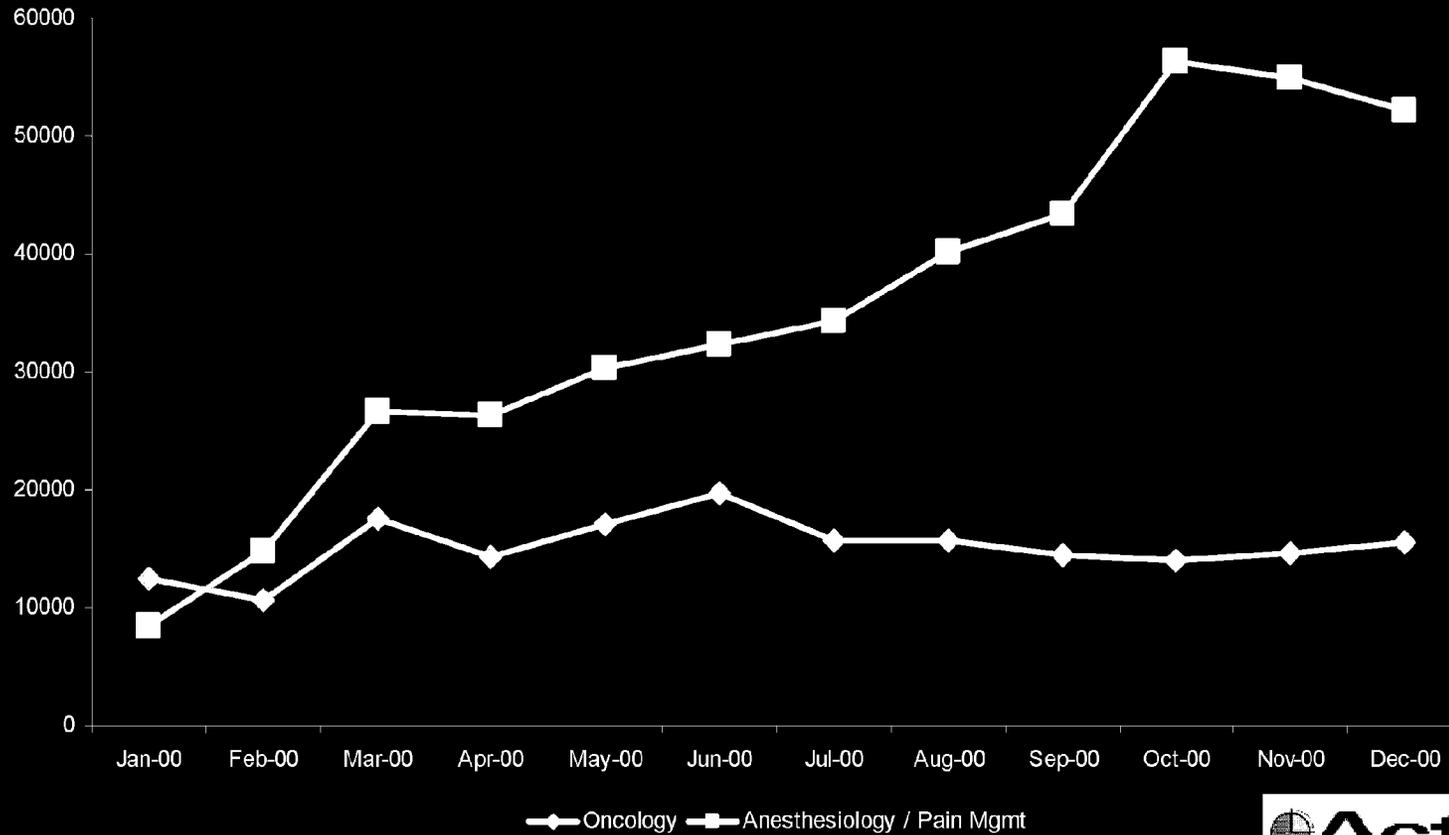
Confidential

CEPH-CT-DS-00191488  
CEP\_TPP\_CTAG10064758

TEVA\_MDL\_A\_05313145

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# Xponent – Monthly Units by Specialty



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# Where are your \$\$ coming from?

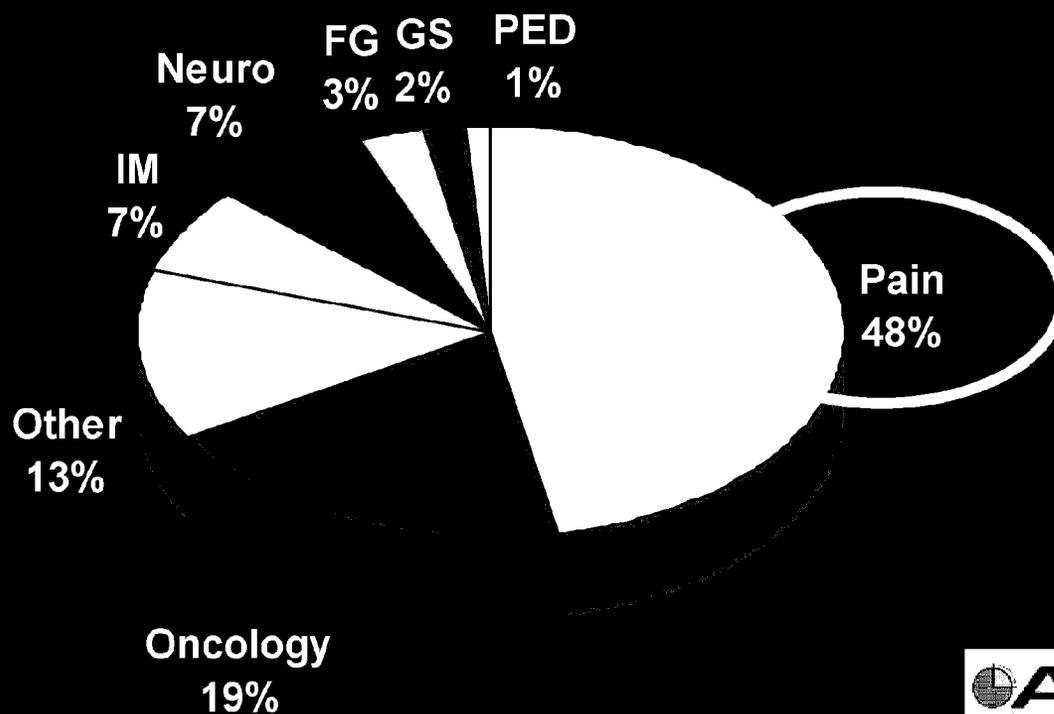
- Oncologists account for:
  - 1 of 4 scripts
  - 1 of 5 units
  - 1 of 6 \$\$
- Pain Specialists / Anesthesiologists
  - Account for 2 of 5 scripts/units/\$\$
- Pain / Anes, Neurology and “Other” all growing at a faster rate than Oncology
- Targeting, Targeting, Targeting



# Actiq Decile Analysis

## Xponent – Physician Prescribers

Top Five Decile Prescribers YTD - Nov 2000  
(n=98)



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(oral transmucosal  
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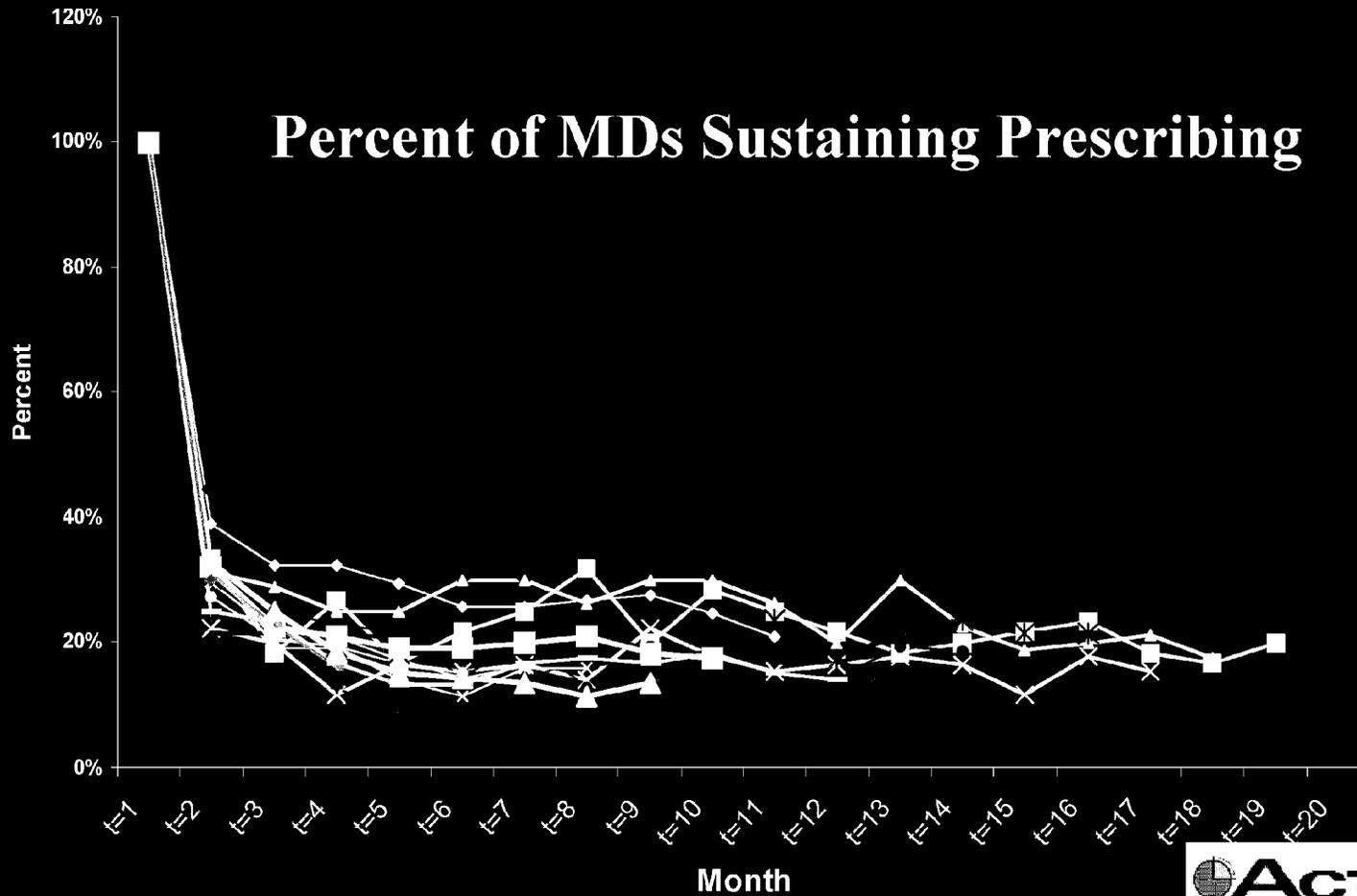
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# Actiq Prescriber Retention Rate



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# Prescriber Retention Research

Performed in February 2000

## Results:

- Efficacy not questioned
  - Lead product “like” – rapid onset
- Factors limiting use
  - Lead product “dislikes” – titration, cost
  - Reimbursement and availability hassles
  - Difficult to change prescribing habits



# Market Drivers

<u>Market Drivers</u>	<u>Jan 2000</u>	<u>Dec 2000</u>	<u>Trend</u>
TRx	864	2,534	↑
RX Size	38 units/ RX	55 units/ RX	↑
Average Selling Price	\$8.01	\$10.03	↑
Total Prescribers	282	636	↑
Units/ MD	129	210	↑
Average Retention Rate	21%		



# IV. Key Issues, Strategies and Tactics



# Key Marketing Issues

1. Lack of meaningful, focused positioning and message
2. Low awareness of Actiq due to limited promotional support
3. Logistical barriers to product adoption that restrict access and prescribing
4. Lack of knowledge about BTP and Actiq
5. Prescriber retention



# 1. ISSUE: Lack of meaningful, focused positioning and message

- Minimal advertising
- Poor initial concepts (“iceberg” and “unit”)
  - “Iceberg” and “Unit” concepts
    - Focused on BTP and delivery system only
    - Lacked features & benefits
    - Did not provide meaningful reason to prescribe



# “Iceberg” Concept



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fentanyl citrate)

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# “Unit” Concept

**NOW AVAILABLE**  
A DELIVERY  
SYSTEM DESIGNED TO MAKE  
A DIFFERENCE

Breakthrough oral transmucosal delivery

**Actiq<sup>®</sup>** (oral transmucosal  
fentanyl citrate)

#### Important Warnings



- > Only for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.
- > Because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates, Actiq is contraindicated in the management of acute or postoperative pain.
- > This product must not be used in opioid non-tolerant patients.
- > Instruct patients/caregivers Actiq can be fatal to a child. Keep open units from children and discard properly.

See boxed warning and full prescribing information on following pages.

Actiq is a registered trademark of Amgen Corp.

 Abbott Laboratories Inc.  
Molecular Products Division  
Abbott Park, IL 60064-1158  
1-800-ABBOTT-1

 **Actiq<sup>®</sup>**  
(oral transmucosal  
fentanyl citrate)

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# 1. ISSUE: Lack of meaningful, focused positioning and message

## STRATEGY

- Re-launch Actiq with revised branding and positioning that provides a meaningful, focused positioning and message



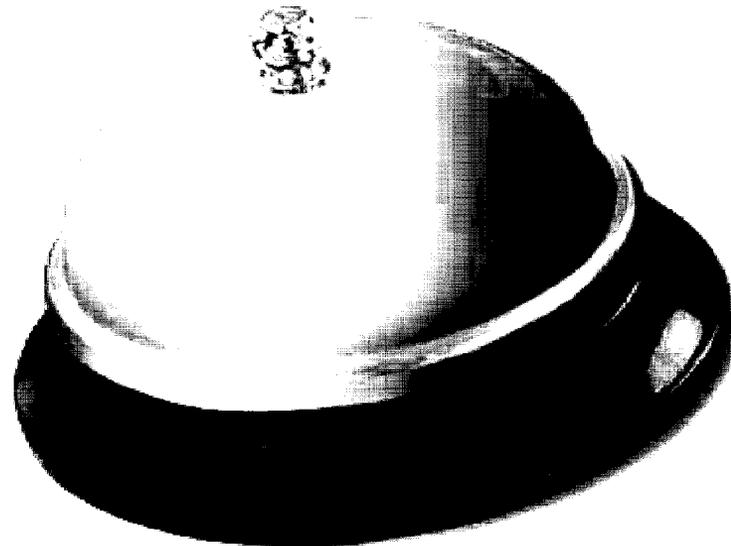
# 1. ISSUE: Lack of meaningful, focused positioning and message

## TACTIC

- New Concept developed (“Bell”)
  - Tested among Oncologists and APMs
  - Provides two key messages and a meaningful reason to prescribe
    - “Bell” and “Relief on demand” convey
      1. Rapid onset
      2. Personal pain control
- Awaiting FDA approval



B R E A K T H R O U G H C A N C E R P A I N



Relief on demand.



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## 2. ISSUE: Low awareness

- Limited promotional support
  - Limited field presence for initial 1999 launch (20 reps)
  - Lack of presence at major conventions
  - Lack of advertising in professional journals
  - No direct mail to physicians to support field efforts
  - Limited \$\$ for MEPs
  - Limited \$\$ for CME programs



## 2. ISSUE: Low awareness

### STRATEGY

- Improve / Increase direct promotional reach and frequency
- Establish indirect and semi-direct promotional efforts



## 2. ISSUE: Low awareness

### TACTICS

- Upgrade field personnel and refine target audience
- Establish a presence at major conventions
  - Conventions we will have a presence at THIS year:
    - American Academy of Pain Medicine (Feb)
    - American Pain Society (April)
    - American Society of Clinical Oncology (May)
    - Oncology Nursing Society (May)
    - American Academy of Pain Management (Sept)
    - American Society of Anesthesiology (Oct)
  - MLs to provide additional presence at regional meetings



A new  
standard bearer in  
the evolving world of pain  
management.



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## 2. ISSUE: Low awareness

### TACTICS (cont'd)

- Media Plan (journal advertisements)
  - May books targeted
  - Professional Journals we will advertise in THIS year:
    - Journal of Clinical Oncology
    - Oncology
    - Oncology Times
    - Oncology Nurses Forum
    - Journal of Pain
    - Journal of Pain and Symptom Management
    - Pain Medicine
    - Pain Digest





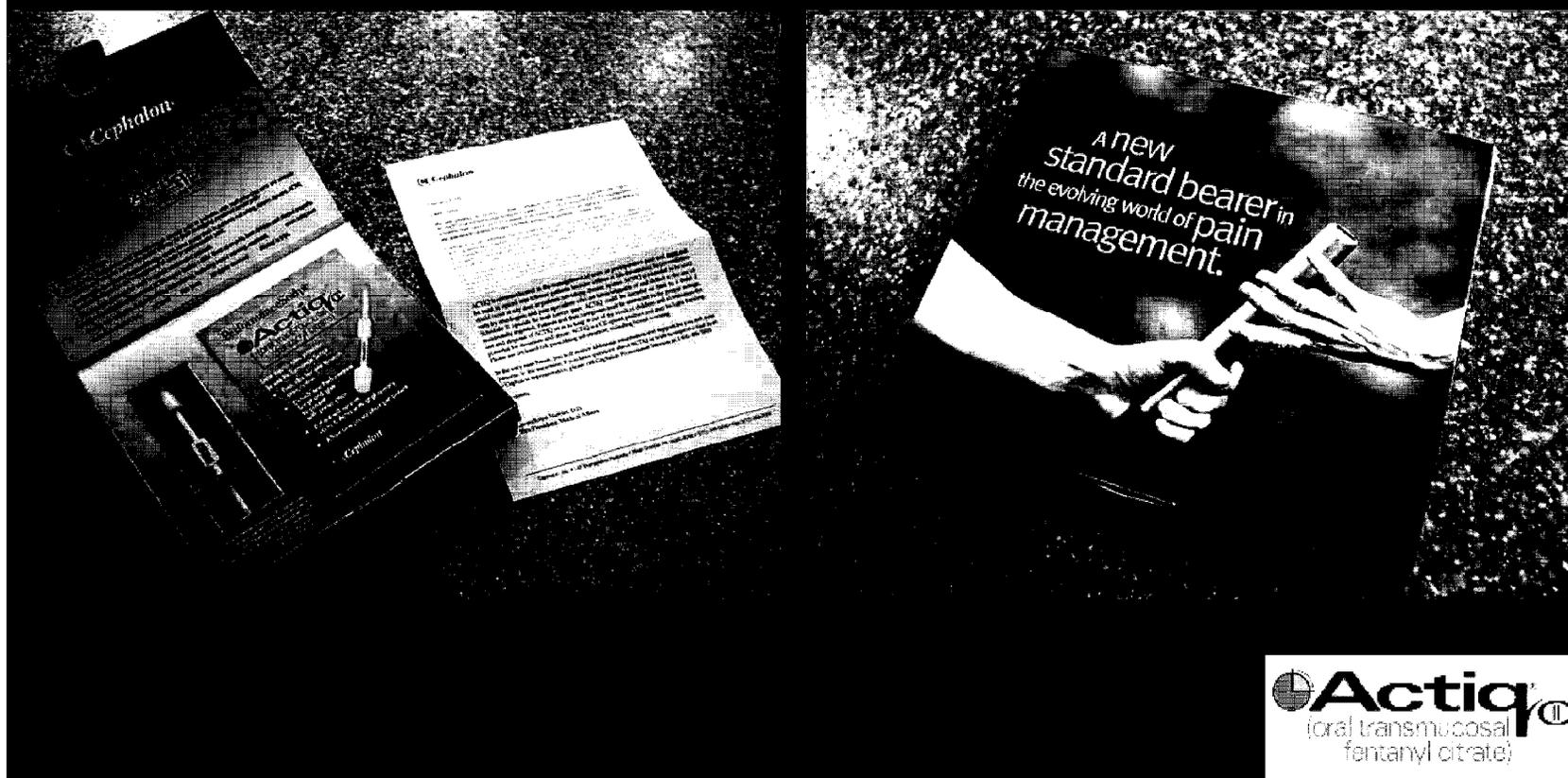
## 2. ISSUE: Low awareness

### TACTICS (cont'd)

- Website upgrade
  - Targeted for May / June
- Direct Mail Campaign
  - First mailing targeted for April
  - Two additional mailings (June and Sept)



# March 2001 Direct Mail Effort



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## 2. ISSUE: Low awareness

### TACTICS (cont'd)

- Enhance speaker advocacy and expand speakers bureau
  - Develop extranet site (targeted for April / May)
  - Two Regional Consultants meetings planned for June
- Increase MEP activity
  - Big \$\$ driving these programs
  - Must maximize impact (ROI)
  - Right: audience / message / speaker / format



## 2. ISSUE: Low awareness

### TACTICS (cont'd)

- Increase CME activity
  - Promoted through direct mailings and sales force



## 2. ISSUE: Low awareness

### TACTICS (cont'd)

- Teletopics
  - Dr. James Cleary - “New Algorithms for Pain Management”
    - Dates in May, June, Sept, Oct
  - Content adapted to CD ROM for CME self-study
- “Profiles in Pain Management”
  - Quarterly newsletter / CD ROM self-study
  - Current hot topics / case studies / reprints



## 2. ISSUE: Low awareness

### TACTICS (cont'd)

- Regional Symposia
  - Targeted for Fall 2001
  - Targeting 3 metropolitan areas
    - If successful, may expand sites
  - Topics to be identified and may include:
    - MSIR v. Actiq study
    - Dr. Forest Tennant Survey Research
  - Content will be adapted to:
    - CD ROM self-study
    - Teleconferences



## 2. ISSUE: Low awareness

### TACTICS (cont'd)

- “A Nurse’s Guide to Breakthrough Pain”
  - Distributed through 3<sup>rd</sup> party to ONS and AAPMNS members
- Four page write-up of Dr. Forest Tennant’s Survey Research
  - Presented at the AAPM National Conference in February 2001



## 2. ISSUE: Low awareness

### TACTICS (cont'd)

- CME Library
  - ProfilesinPainManagement.com
  - Online self-study
    - Accessible 24/7
    - Every adapted CME program will be accessible
- Other CE programs to be developed



### 3. ISSUE: Logistical barriers

- Wholesalers not adequately stocked at various points during 2000
- Retail pharmacies reluctant to stock
- Insufficient and inconsistent reimbursement



# 3. ISSUE: Logistical barriers

## STRATEGY

- Maintain appropriate wholesaler inventories
- Market research to identify problems / trends in retail pharmacies
- Facilitate reimbursement



# 3. ISSUE: Logistical barriers

## TACTICS

- Distribution and Logistics Department
  - Ensuring wholesalers are adequately stocked through new / improved relationships
  - New distribution warehouse (DDN) ensures rapid shipment of product to wholesalers
    - 2 day turnaround (versus 2-3 weeks prior)
  - Identifying options to secure product availability at retail pharmacies



# 3. ISSUE: Logistical barriers

## TACTICS (cont'd)

- Market research to identify problems / trends in retail pharmacies (completed Jan 2001)
  - Surveyed 201 retail pharmacies
    - 99 independent / small chain; 102 large chain
  - Results:
    - 7% reported stocking Actiq; no difference b/w pharmacy types
    - Non-stocking pharmacies
      - 65% reported “no scripts” as primary reason
      - 35% reported being “not aware” as primary reason
  - Conclusion:
    - Retail pharmacies will stock as demand increases and awareness improves



# 3. ISSUE: Logistical barriers

## TACTICS (cont'd)

- Identified new vendor for PAP / Reimbursement Program
  - Pracon replaces CRC
  - Will assume responsibilities March 2001
    - Details in workshop
  - Accessible through Cephalon Professional Services line (800-896-5855)
  - PAP will only support patients with malignancies
  - Reimbursement Program will support all patients



## 4. ISSUE: Lack of knowledge

- BTP not well understood
- Pain management not primary concern of Oncologists
- Misperceptions about cost of Actiq
- Poor understanding of the relative potency of Actiq



# 4. ISSUE: Lack of knowledge

## STRATEGY

- Create advocacy among key thought leaders
- Educate clinicians about BTP and Actiq
- Support aggressive treatment of BTP with key pain associations via PR efforts



# 4. ISSUE: Lack of knowledge

## TACTICS

- MLs (and PCSs) to develop Actiq speaker bureau
- CME programs to assist in clinician education (previously listed)



# 4. ISSUE: Lack of knowledge

## TACTICS (cont'd)

- Medical Education Programs
  - Discovery International to assist in coordination
  - Minimum 5 per territory (240 total MEPs)
  - Topics for MEPs
    - Effective Management of BTCP
    - Effective Management of BTP in Patients with Metastatic Bone Pain
    - Management of BTP in the Difficult Radiation Patient
    - Management of BTP in the New JCAHO Standards



# 4. ISSUE: Lack of knowledge

## TACTICS (cont'd)

- Promotional Materials
  - Dosing Guide (Feb 2001)
  - Revised Sales Aid (March 2001)
    - New sales aid (target June)
  - Revised PCS Coupon
    - New PCS Coupon ( target June 2001)
  - Temporary Booth Panel / Table Top Display graphics (March 2001)
    - New Booth Panel / table top (target June 2001)



# 4. ISSUE: Lack of knowledge

## TACTICS (cont'd)

- Promotional Materials (cont'd)
  - 800# Magnet (March 2001)
  - 800# Rolodex Card (March 2001)
  - Revised Product Monograph (target 2<sup>nd</sup> quarter)
  - PAP / Reimbursement Program Guide (target 2<sup>nd</sup> quarter)
  - FAQ for Clinicians (target 3<sup>rd</sup> quarter)
  - FAQ for Patients (target 3<sup>rd</sup> quarter)
  - Reprints to be submitted for review



# Dosing Guide

**ACTIQ DOSING GUIDE**

For the management of moderate to severe cancer pain in opioid-tolerant patients.

- Fast onset of action
- No respiratory depression
- No sedation
- No tolerance or physical dependence
- No withdrawal symptoms

**ACTIQ IS UNIQUELY DESIGNED FOR BREAKTHROUGH CANCER PAIN IN OPIOID-TOLERANT PATIENTS**

The ACTIQ unit contains fentanyl citrate in a small drug reservoir in a hard, plastic shell.

**The ACTIQ Unit:**

ACTIQ delivers fentanyl to the cancer patient via the oral transmucosal system.

With ACTIQ, pain relief can begin in 15 minutes, but patients may not experience full relief for up to 45 minutes after finishing an ACTIQ unit.

**Similar Distribution across Dosage Strengths**

ACTIQ doses following successful titration were similarly distributed over all six dosage strengths.

Dosage Strength	Percentage
250 mcg unit	16%
500 mcg unit	14%
750 mcg unit	21%
1000 mcg unit	20%
1500 mcg unit	15%

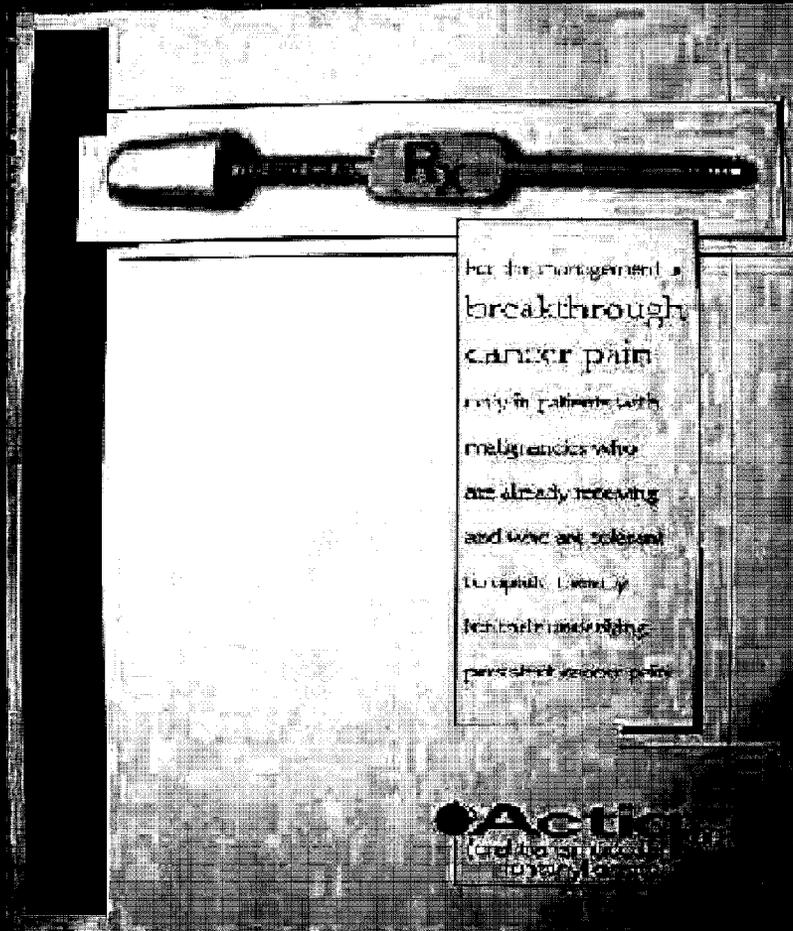
The mean maintenance dose of ACTIQ was found to be 750 mcg for patients successfully titrated in a multicenter, double-blind efficacy study.

Patients over 65 years of age titrated to a mean maintenance dose that was about 200 mcg less than the mean dose to which younger adult patients were titrated.

**Actiq<sup>®</sup>**  
(oral transmucosal fentanyl citrate)

**Actiq<sup>®</sup>**  
(oral transmucosal fentanyl citrate)

# Revised Sales Aid



**Actiq**<sup>®</sup>  
(oral transmucosal  
fentanyl citrate)

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P-18898\_00064

# Revised PCS Coupon

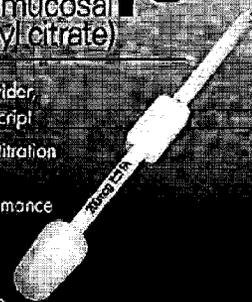
PerformanceScript<sup>®</sup>

**Actiq<sup>®</sup>**  
(oral transmucosal fentanyl citrate)

Dear health care provider,  
To use Performance Script

- Prescribe for one titration prescription
- Detach one Performance Script and give to patient with prescription
- Patient will receive up to 6 Actiq units at pharmacy
- Allow one prescription per patient

*Cephalon*



**Actiq<sup>®</sup>**  
(oral transmucosal fentanyl citrate)

This sample of ACTIQ is provided to you as a service by your prescriber and Cephalon, Inc. When you present this card along with a completed and signed regulation prescription form, the pharmacist is authorized to dispense 6 units of ACTIQ. Follow the dosage instructions given to you by your prescriber. See your physician for important product information.

**To Pharmacist:** See back panel for additional instructions.

PerformanceScript<sup>®</sup>

*Cephalon* **Actiq<sup>®</sup>**  
(oral transmucosal fentanyl citrate)

CARRIER #	GROUP #	IDENTIFICATION	SUFFIX
ACT2	0001	999999999	01

PerformanceScript<sup>®</sup>

PCS EXPIRES 12/2001

© 2001 CEPHALON, INC. ACTIQ® JAN 2001 ALL RIGHTS RESERVED. PRINTED IN U.S.A.  
VOID WHERE PROHIBITED BY LAW. PRODUCT DISPENSED AS SAMPLE PURSUANT TO TERMS OF COUPON.  
SHALL NOT BE SUBMITTED TO ANY THIRD PARTY (PROV, PUBLIC OR PRIVATE) IN A MEDICAL  
PERFORMANCE SCRIPT IS A REGISTERED MARK OF ANESTHETICS  
ACTIQ IS A REGISTERED TRADEMARK OF ANESTHETICS, A WHOLLY OWNED SUBSIDIARY OF CEPHALON, INC.

**Actiq<sup>®</sup>**  
(oral transmucosal fentanyl citrate)

Confidential Treatment Requested by Cephalon, Inc.  
CONFIDENTIAL PER STIPULATION AND PROTECTIVE ORDER

Confidential

CEPH-CT-DS-00191530  
CEP\_TPP\_CTAG10064800

TEVA\_MDL\_A\_05313187

P-18898\_00065

# 800# Magnet and Rolodex Card



## Professional Services

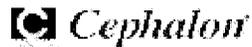
Patient Reimbursement Assistance Program

Welcome Kit Hotline

Medical Information

**1-800-896-5855**

Please see attached full prescribing information including black box warning.



ACT 039 Feb. 2001



# Give-Aways



**Actiq**<sup>®</sup>  
(oral transmucosal  
fentanyl citrate)

Confidential Treatment Requested by Cephalon, Inc.  
CONFIDENTIAL PER STIPULATION AND PROTECTIVE ORDER

**Confidential**

CEPH-CT-DS-00191532  
CEP\_TPP\_CTAG10064802

**TEVA\_MDL\_A\_05313189**

P-18898\_00067

# 4. ISSUE: Lack of knowledge

## TACTICS (cont'd)

- PR efforts
  - New firm identified with experience in pain management (Cooney Waters)
  - 2001 plans to be finalized in March



# 5. ISSUE: Prescriber retention

- Average retention rate 21%
- Titration process perceived as cumbersome
  - Often multi-step process
  - Patient education required
  - Product availability concerns
  - Reimbursement questioned
- Four previous issues
  - Poor positioning and message
  - Low awareness
  - Logistical barriers
  - Lack of knowledge



# 5. ISSUE: Prescriber retention

## STRATEGY

- Educate clinicians
  - Provide clear dosing directions
  - Provide patient education materials
  - Provide PAP / reimbursement info
  - Assurance product availability
- Address four previous issues



# 5. ISSUE: Prescriber retention

## TACTICS

- Dosing directions
  - Dosing Guide
  - MIRF
    - Written response for relative potency
    - Reprints (Lichter study, phase IV 006 Titration study)
  - MEPs
- Patient education materials
  - Welcome kit / patient education video
  - FAQ for Patients



# 5. ISSUE: Prescriber retention

## TACTICS (cont'd)

- Provide PAP / reimbursement guide
  - Managed Care Department
- Drive pharmacy stocking in key retail pharmacies
  - Distribution and Logistics Department currently identifying options to secure product availability at retail pharmacies



# V. Keys to Success

Physician Targeting

Simplifying Titration

MEPs

CME Programs

